

REMARKS

Applicant's Election

Applicant appreciates the Examiner's acknowledgement of Applicant's election with traverse of Group I, claims 1-9 in its reply filed on 3/31/08 and the compound in the reply filed on 7/25/08.

Expansion of Election of Species Requirement

Applicant appreciates the Examiner's acknowledgement that the prior art at the time of the present invention was such that it didn't anticipate or render obvious the elected specie.

Rejection of Claims 1-9 under 35 U.S.C. § 112, First Paragraph

The Examiner has rejected claims 1-9 under 35 U.S.C. 112, first paragraph for the reasons of record. Specifically the Examiner has stated that the Applicant has not disclosed how one skilled in the art can use the method of inhibiting an ubiquitin isopeptidase in a cell by contacting a cell with a compound having an α,β -unsaturated ketone with a sterically accessible electrophilic- β carbon that is not a cyclopentenane prostaglandin of the J family. In contrast, the Examiner has stated that the specification is enabling for making the compounds of the generic formula of claim 9 and for using the compound detailed in Example 1. Applicants respectfully traverse this rejection.

As stated above, the Examiner has stated that the specification is enabling for the use of the exemplary compound detailed in Example 1 ($\Delta 12$ -PJ₂) but not for the broad class of compounds described in claim 1. Applicant responds that all compounds described in claim 1 may be used in the same way as $\Delta 12$ -PJ₂.

35 U.S.C. 112, first paragraph requires the specification to describe to one skilled in the art how to make and use an invention. However, it is not necessary to "enable one of ordinary skill in the art to make and use a perfected, commercially viable embodiment ...". *CFMT, Inc. v. Yieldup Int'l Corp.*, 349 F.3d 1333, 1338, 68 USPQ2d 1940, 1944 (Fed. Cir. 2003) Applicant is also not required to provide detailed procedures for making and using each and every embodiment of the invention if the description of the invention itself is sufficient to permit one skilled in the art to make and use the invention. Herein, the Examiner has stated that the specification is enabling for the compounds of generic claim 9 and one skilled in the art could take the teachings directed to the generic compounds of claim 9 and apply them to the broad classification of compounds of claim 1.

Thus, Applicant respectfully submits that the instant specification provides sufficient examples and guidance related to the use of compounds having an α,β -unsaturated ketone with a sterically accessible electrophilic- β carbon that are not cyclopentenane prostaglandins of the J family so that one of ordinary skill in the art would be enabled to use the instant invention without undue experimentation. As such,

Applicant respectfully requests withdrawal of the rejection of claims 1-9 under 35 U.S.C. 112, first paragraph.

Rejection of claims 1-9 under 35 U.S.C. 102(a)

The Examiner has rejected claims 1-9 as being anticipated by Baker et al. ("Baker") for the reasons of record. Specifically, the Examiner contends that Baker teaches administration of the elected compound to L1210 mouse leukemia cells and "even if the inhibition of ubiquitin isopeptidase was not itself recognized as a pharmacological effect of contacting the elected compound to cells, such an effect is not considered a new therapeutic application since the very contact of the cells with the elected compound, which is well known in the prior art, would also inhibit ubiquitin isopeptidase." Applicant respectfully traverses this rejection.

Applicant respectfully asserts that merely the fact that a certain result or characteristic may occur in the prior art is not sufficient to establish the inherency of that result or characteristic. *In re Rijckaert*, 9 F.3d 1531, 1534, 28 USPQ 2d 1955, 1957 (Fed. Cir. 1993) Additionally, "to establish inherency, the extrinsic evidence 'must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill.'" *In re Robertson*, 169 F.3d 743, 745, 49 USPQ2d 1949, 1950-51 (Fed. Cir. 1999)

Baker is directed to studies done on a telestacean octocoral, *telesto riisei*. It was collected from Pupukea, O'ahu and later in the entrance channel to the Ala Wai boat

harbor. A total of 19 marine coral punaglandins were isolated and examined. According to Baker, the "biological activities of the punaglandins proved to be as varied as those of the mammalian prostanoids." Additionally, of the 19, only two of them, (5 and 7) of the 19 marine punaglandins studied were more potent than corresponding clavulones against cultured L1210 mouse leukemia cells.

Applicant respectfully asserts that, "an invitation to investigate is not an inherent disclosure" where a prior art reference, such as Baker, "discloses no more than a broad genus of potential applications of its discoveries." *Metabolite Labsl., Inc. v. Lab. Corp. of Am. Holdings*, 370, F.3d 1354, 1367, 71 USPQ2d 1081, 1091 (Fed. Cir. 2004) Additionally, in no way does this disclosure, "provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art." *Ex parte Levy*, 17 USPQ 2d 1461, 1464 (Bd. Pat. App. & Inter. 1990) In the instant case, Baker merely mentions that two of the nineteen marine coral punaglandins investigated had an effect in an investigatory leukemia cell line and in no way teaches the use of punaglandins for treatment of leukemia, as only two of the nineteen compounds tested were effective against the cell line. Additionally, in no way does Baker provide any basis for believing that there is consistent inhibition of ubiquitin isopeptidases in cells in light of the inconsistent results after treatment of leukemia cells.

Lastly, Applicant also respectfully directs the Examiner's attention to the broad class of compounds described in claim 1. Punaglandins are merely one sub-set of this

broad classification of compounds, of which Baker only found activity in two of nineteen tested punaglandins. One skilled in the art would have no basis whatsoever for relying on the teachings in Baker to make any type of conclusion about the broad classification of compounds in claim 1.

In light of the above, the teachings of this reference would not direct one skilled in the art to use punaglandins, let alone the broad classification of compounds described in claim 1, to inhibit ubiquitin isopeptidase in a cell. It is therefore the Applicant's position that Baker fails to provide an enabling disclosure for the inhibition of ubiquitin isopeptidase in a cell and in no way has the Examiner provided a rationale or evidence tending to show inherency. In view of the foregoing, Applicant respectfully requests withdrawal of the rejection of claims 1-9 under 35 U.S.C. 102(a).

Concluding Remarks

In view of the above provisional election and arguments, an Office Action on the merits is respectfully requested at an early time.

If the Examiner notes any further matters which would be expedited by a telephonic interview, she is requested to contact Dr. Jennifer M. McCallum at the telephone number listed below.

It is believed that no fees are due in this matter; however, if a fee is due the Commissioner is authorized to charge it to deposit account No. 502679.

Respectfully submitted,

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Date

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